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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,933

12/30/2003

David J. Parins

1001.1676101

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7590

07/21/2009

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MINNEAPOLIS, MN 55403-2420

EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

07/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,933	Applicant(s) PARINS ET AL.	
	Examiner RENE TOWA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-15,17-54 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) 23-54,61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-15,17-22 and 63-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2009 has been entered.
2. This Office action is responsive to an amendment filed May 6, 2009. Claims 1, 3-4, 7-15, 17-54 & 61-67 are pending. Claims 2, 5-6, 16 & 55-60 have been cancelled. Claims 23-54 & 61-62 have been withdrawn. Claims 1, 14 & 21 have been amended.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claim 17** is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a guidewire having an outer tubular member that is selected from a polymer sheath or a coil (i.e. as evidenced by claim 1), does not reasonably provide enablement for a guidewire having an outer tubular member and further comprising a polymer sheath. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant's original specification only provides for a guidewire that includes an outer tubular member that may be a polymer sheath (see fig. 3) or a coil (see fig. 4). As such, the original

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specification fails to teach a guidewire comprising an outer tubular member, which may be a polymer sheath or a coil, and yet further includes a polymer sheath. In view of the foregoing, the Examiner submits that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claim 67** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At line 9 of the claim, the limitation “inner coil” lacks sufficient antecedent basis; For example, there is no prior recitation of this limitation in the claim. Moreover, the limitation “inner coil” should apparently read --metallic coil member--.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 1, 3-4, 7, 12-15, 17, 22 & 63-66** are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian (US 5,178,159) in view of Frisbie et al. (US 5,517,989), and further in view of Little (US 5,313,957).

In regards to **claim 1**, **Christian** discloses a guidewire, comprising:

(a) a core member 203 having a proximal end and a distal end, wherein the core member 203 is generally solid in cross-section;

(b) a metallic tubular member 206 having a proximal end and a distal end and a lumen therebetween, the tubular member 206 disposed about and connected to the distal end of the core member 203, the distal end of the tubular member 206 extending distally beyond the distal end of the core member 203; and,

(c) a coil member 210 connected to and disposed about the tubular member 206; wherein the coil member 210 includes a distal end and a proximal end, and wherein the distal end of the coil member 210 extends distally beyond the distal end of the tubular member 206 (see fig. 12).

In regards to **claim 3**, Christian discloses a guidewire wherein the proximal end of the coil member 210 is positioned distal of the distal end of the core member 203 (see fig. 12).

In regards to **claim 4**, Christian discloses a guidewire wherein the proximal end of the tubular member 206 fits over the distal end of the core member 203 (see fig. 12).

In regards to **claim 12**, Christian discloses a guidewire wherein the tubular member 206 has a hemispherical cross section (see fig. 12).

In regards to **claim 13**, Christian discloses a guidewire wherein the tubular member 206 has a circular cross section (see fig. 12).

In regards to **claim 14**, Christian discloses a guidewire comprising:

(a) a core member 203 including a proximal portion having a proximal end and a distal portion having a distal end, wherein the core member 203 is generally solid in cross-section; and

(b) a distal assembly (206, 210) including a tubular member 206 having an inner surface adapted for connection to the distal portion of the core member 203, and an outer surface, and a coil member 210 connected to the tubular member 206;

wherein the distal assembly (206, 210) is connected to the distal portion of the core member 203 such that a portion of the distal assembly extends distally beyond the distal end of the core member 203 (see fig. 12).

In regards to **claim 15**, Christian discloses a guidewire wherein the distal assembly is connected to the distal portion of the core member 203 such that a portion of the tubular member 206 extends distally beyond the distal end of the core member 203 (see fig. 12).

In regards to **claim 22**, Christian discloses a guidewire wherein the tubular member 206 has a circular cross section (see fig. 12).

In regards to **claim 63**, Christian discloses a medical device wherein the proximal end of the coil 2 is distal to the distal end of the core member 203 (see fig. 12).

In regards to **claim 64**, Christian discloses a medical device wherein the proximal end of the coil 2 is distal to the distal end of the tubular member 206 (see fig. 12).

In regards to **claim 65**, Christian discloses a guidewire wherein the proximal end of the coil 2 is distal to the distal end of the core member 203 (see fig. 12).

In regards to **claim 66**, Christian discloses a guidewire wherein the proximal end of the coil 2 is distal to the distal end of the tubular member 206 (see fig. 12).

Christian disclose a guidewire, as described above, that fails to explicitly teach a core member that is connected to the inner surface of the tubular member. Christian further discloses

a guidewire, as described above, that fails to explicitly teach an outer member or polymer sheath disposed around the core member.

However, **Frisbie et al.** teach that it is known to connect a core member 34 to a tubular member 33 via soldering in order to stably hold the sections of the guidewire together (see fig. 3; col. 5, lines 14-18).

Moreover, **Little** discloses a guidewire 12 comprising an outer member 20 disposed around the guidewire 12; wherein the outer member 20 is a polymer sheath (see col. 3, lines 64-68; col. 4, lines 1-14).

In regards to **claims 1, 3-4, 7, 12-15, 17, 22 & 63-66**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Christian with a core member that is connected to the tubular member as taught by Frisbie et al. in order to stably hold the sections of the guidewire together.

Similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Christian as modified by Frisbie et al. with an outer member as taught by Little in order to increase the lubricity of the guidewire.

9. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Christian ('159) in view of Frisbie et al. ('989), Little ('957), and further in view of Palmer et al. (US 6,544,231).

Christian as modified by Frisbie et al. and Little discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Christian as modified by Frisbie et al. and Little with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

10. **Claims 9-10 & 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian ('159) in view of Frisbie et al. ('989), Little ('957), and further in view of Cook et al. (US 5,213,111).

Christian as modified by Frisbie et al. and Little discloses a guidewire, as described above, that fails to teach connecting the tubular member through crimping.

However, **Cook et al.** disclose a guidewire wherein a coil member 2 is connected to a core member through crimping (see column 3/lines 13-16).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guidewire of Christian as modified by Frisbie et al. and Little with a connecting process as taught by Cook et al. in order to hold the elements together in a friction-fit fashion.

11. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Christian ('159) in view of Frisbie et al. ('989), Little ('957), Cook et al. ('111), and further in view of Palmer et al. (US 6,544,231).

Christian as modified by Frisbie et al., Little and Cook et al., above, discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Christian as modified by Frisbie et al., Little and Cook et al., above, with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

12. **Claims 18 & 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian ('159) in view of Frisbie et al. ('989), Little ('957), and further in view of Palmer et al. (US 6,544,231).

Christian as modified by Frisbie et al. and Little above, discloses a guidewire, as described above, that fails to teach the process of laser welding or soldering.

However, **Palmer et al.** disclose a medical instrument wherein a coil is bonded to a metallic tubular structure through laser welding (see column 4/lines 16-18).

Since it is known to provide metallic tubular and core members, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to attach the guidewire of Christian as modified by Frisbie et al. and Little above, with a connecting process as taught by Palmer et al. in order to tightly fuse metal elements together.

13. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Christian ('159) in view of Frisbie et al. ('989), Little ('957), and further in view of Buchbinder et al. (US 4,815,478).

Christian as modified by Frisbie et al. and Little above, discloses a guidewire, as described above, that fails to teach a guidewire wherein the tubular member comprises a C-shaped cross section.

However, **Buchbinder et al.** disclose a guidewire comprising a tubular member 41 wherein the tubular member 41 comprises a C-shaped cross section (see figs. 3-4).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guidewire of Christian as modified by Frisbie et al. and Little above to include a C-shaped cross section as taught by Buchbinder et al. in order to increase the flexibility of the guidewire in the distal direction for better steerability.

Allowable Subject Matter

14. **Claim 67** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

15. Applicant's arguments filed May 6, 2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736